K 021250

4. Summary of Safety and Effectiveness

OCT 2 4 2002

4.1 Identification of Device

Trade Name: MK-dent® Push Button Highspeed Handpiece, 4 Holes, Models: HS 2012 (Standard Head) and HS 2014 (Small Head)

Common/Usual Name: Handpiece, air-powered, dental

Classification Name: Dental handpiece

Device Class: Class I

Product Code 76 EFB

4.2 Equivalent Device

Equivalent legally marketed device: KaVo 625 Dental Handpiece (K760929)

4.3 Indications for Use

The device is an air-powered dental handpiece for use by a trained professional in general dentistry.

4.4 Description of Device

The MK-dent® HS 2012/2014 shares virtually all specifications and design characteristics of the predicate devices. This was done intentionally by the designers and engineers. The only major design change refers to the strength of the auto chuck mechanism. By increasing the spring strength, we have created a more reliable version compared to KaVo 625. By increasing the bur retention strength from 6 lbs (as with the predicate device) to 8 lbs. (MK-dent® HS 2012/2014) we have been able to vastly reduce the odds of a bur prematurely ejecting from the handpiece. A few minor changes to the predicate device which do not affect the performance but we feel make the handpiece convenient to use are as follows: Reduction in the weight of the handpiece to 2 oz.. This reduces operator hand fatigue. Softening the knurling on the handle. This allows dirt, blood and salvia to be more easily removed from the body shell of the handpiece, thus allowing better conformity to sterilization procedures. It also provides better tactile sense to the operator while wearing gloves.

4.5 **Safety and Effectiveness**, comparison to predicate device

Element of Comparison	- KaVo 625 Handpieces (K760929)	MK-dent® HS 2012/2014
Intended Use	General dentistry by trained professional	SAME
Materials: - Handpiece housing - Turbine housing - Turbine housing cap	 - Copper-tin bronze - Nickel silver CDA alloy - Stainless steel	SAME

- Plating	- Chrome	
Energy Source	Air pressure, 30-32 psi	SAME
Sterilization	Steam autoclave or ETO	Steam autoclave

4.6 Conclusion

In all respects, the MK-dent® HS 2012/2014 is substantially equivalent to one or more air-powered dental handpieces currently marketed in the USA. The handpiece is constructed of materials of the same specifications as the predicate device to ensure biocompatibility. The handpiece conforms to applicable ISO standards.
The ability to repeatedly adequately sterilize the devices has been confirmed by validation protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Dr. Martina Günderoth
C.R.C. Partnerschaftsgesellschaft
Katharinenstr. 5
23554 Lübeck,
GERMANY

Re: K021250
Trade/Device Name: MK-dent® HS 2012/2014
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBF
Dated: August 8, 2002
Received: August 19, 2002

Dear Dr. Günderoth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indications for Use

510(k) Number _____

Device Name: MK-dent® HS 2012/2014

Indications for Use: The device is an air-powered dental handpiece for use by a trained professional in general dentistry.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over the Counter Use_____
(Per 21 CFR 801.109)

RSpitz DDS for Dr Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K021250